DOI: https://doi.org/10.61841/eea7qz42 Publication URL: https://jarmhs.com/MHS/index.php/mhs/article/view/539

COMPARISON DIAGNOSTIC ACCURACY OF ULTRASONOGRAPHY ELASTOGRAPHY FOR DETECTING LIVER FIBROSIS COMPARED TO LIVER BIOPSY: A COMPREHENSIVE SYSTEMATIC REVIEW AND META-ANALYSIS STUDIES

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To Cite This Article: Firmansyah, A. ., & Utama, A. . (2024). COMPARISON DIAGNOSTIC ACCURACY OF ULTRASONOGRAPHY ELASTOGRAPHY FOR DETECTING LIVER FIBROSIS COMPARED TO LIVER BIOPSY: A COMPREHENSIVE SYSTEMATIC REVIEW AND META-ANALYSIS STUDIES. Journal of Advanced Research in Medical and Health Science (ISSN 2208-2425), 10(10), 7-16. https://doi.org/10.61841/eea7qz42

ABSTRACT

Background: *Liver fibrosis significantly impacts disease outcomes in chronic liver disease. While liver biopsy has long been the gold standard for assessing and staging fibrosis, non-invasive ultrasound-based methods are emerging as valuable alternatives. The aim of this study is to systematically review and conduct a meta-analysis to compare the diagnostic accuracy of ultrasound elastography with liver biopsy for detecting liver fibrosis based on literatures in the last 10 years.*

Method*: A systematic review and meta-analysis were conducted according to PRISMA 2020 guidelines using the PICO framework. Rigorous screening, data extraction, risk of bias assessment, and statistical analysis were performed to investigate diagnostic accuracy of ultrasonography elastography for detecting liver fibrosis compared to liver biopsy.*

Results*: A total of 32 articles were retrieved from online databases (PubMed, SagePub, Nature and Cochrane). After three rounds of screening, seven articles directly relevant to the meta-analysis were selected for full-text reading and analysis.*

Conclusion: *Liver fibrosis significantly impacts disease outcomes in chronic liver disease. While liver biopsy has long been the gold standard for assessing and staging fibrosis, non-invasive ultrasound-based methods like shear wave elastography are emerging as valuable alternatives.*

KEYWORDS: *Ultrasonography elastography, liver fibrosis, liver biopsy*

INTRODUCTION

Liver disease is a global health concern, with viral liver diseases affecting approximately 500 million people worldwide, contributing to nearly one million deaths annually from complications such as cirrhosis and hepatocellular carcinoma. The prognosis and treatment outcomes for these patients are closely linked to the stage of liver fibrosis, particularly in those with hepatitis C.[1,2]

Liver fibrosis results from chronic liver damage, marked by the excessive accumulation of extracellular matrix proteins (ECM) that disrupt the normal hepatic structure. Over time, this leads to hepatocyte damage, portal hypertension, impaired liver function, and ultimately liver failure or hepatocellular carcinoma. Liver fibrosis can be caused by various factors, including viral hepatitis (HBV and HCV), excessive alcohol intake, non-alcoholic fatty liver disease (NAFLD), autoimmune hepatitis, and cholestatic liver diseases.[3–5]

Liver fibrosis is a critical factor in determining disease outcomes in patients with chronic liver disease (CLD). The degree of fibrosis significantly impacts both the prognosis and the management of the disease, as it influences treatment decisions and long-term outcomes. Early detection of liver fibrosis is essential, as untreated fibrosis can progress to severe complications such as cirrhosis and hepatocellular carcinoma. Therefore, accurately staging liver fibrosis is crucial for effective patient care and intervention.[6–8]

For many years, liver biopsy has been considered the gold standard for assessing and staging liver fibrosis. This procedure provides direct histological evidence of the extent of fibrosis, offering valuable insights into the condition's severity. However, liver biopsy is invasive, often painful, and carries potential risks such as bleeding, pneumothorax, and even death. Moreover, the accuracy of biopsy results can be compromised by sampling errors and variability in interpretation between different observers, limiting its reliability.[9–11]

To address these limitations, non-invasive methods for evaluating liver fibrosis have been developed. These methods primarily include serological tests and advanced imaging techniques, which provide less invasive alternatives to biopsy. The goal of these non-invasive approaches is to reduce the need for biopsies while maintaining diagnostic accuracy, improving patient safety and comfort in the process.[12,13]

Among the non-invasive imaging techniques, ultrasound-based methods, particularly shear wave elastography (SWE), have revolutionized the clinical management of liver fibrosis. SWE measures liver stiffness, offering an indirect assessment of fibrosis that correlates well with biopsy results. As a result, SWE has become an essential tool in reducing the number of liver biopsies performed, helping clinicians assess fibrosis without subjecting patients to invasive procedures.[14–16]

Shear wave elastography includes several techniques, such as transient elastography (TE) and Acoustic Radiation Force Impulse (ARFI). These methods provide reliable, non-invasive assessments of liver stiffness, making them effective alternatives to traditional liver biopsy. As the technology continues to evolve, SWE has the potential to further improve the early detection and management of liver fibrosis, offering a safer and more accessible diagnostic approach for patients with chronic liver disease.[17,18]

The aim of this study is to systematically review and conduct a meta-analysis to compare the diagnostic accuracy of ultrasound elastography with liver biopsy for detecting liver fibrosis based on literatures in the last 10 years.

METHODS

This systematic review meta-analysis was conducted in adherence to the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analysis) guidelines. This study used the PICO (Population, Intervention, Comparator, and Outcomes) framework.

The PICO framework used in this study consists of Population: Adult patients with chronic liver disease (CLD) being evaluated for liver fibrosis; Intervention: Ultrasound elastography (SWE), including techniques like transient elastography (TE) and Acoustic Radiation Force Impulse (ARFI); Comparison: Liver biopsy as the gold standard for diagnosing liver fibrosis; Outcome: Diagnostic accuracy (sensitivity, specificity) of ultrasound elastography for detecting liver fibrosis compared to liver biopsy.

ELIGIBILITY CRITERIA

This systematic review and meta-analysis included studies that focused on adult patients with chronic liver disease (CLD) being evaluated for liver fibrosis, regardless of the underlying cause of liver disease. Eligible studies assessed the use of ultrasound elastography techniques, including shear wave elastography (SWE), transient elastography (TE), or Acoustic Radiation Force Impulse (ARFI), and provided data comparing their diagnostic accuracy to liver biopsy. Studies were included if they reported sensitivity, specificity, and other diagnostic performance metrics of elastography in detecting liver fibrosis, and had published results in peer-reviewed journals.

Studies were excluded if they did not specifically evaluate ultrasound elastography in the context of liver fibrosis diagnosis or lacked a comparison with liver biopsy. Case reports, non-peer-reviewed articles, and studies with fewer than 10 participants were excluded to ensure reliable and robust data. Additionally, studies that focused on pediatric populations, non-CLD conditions, or did not provide detailed diagnostic outcomes related to liver fibrosis were not included.

DATA SOURCES AND SEARCH STRATEGY

Authors utilized various data sources and search strategies, including the Medical Subject Headings (MeSH) database. A comprehensive search was conducted across PubMed, SagePub, Nature, and Cochrane to identify relevant studies. Keywords included in this study ultrasonography elastography, liver fibrosis, liver biopsy. Boolean operators were employed to combine these terms effectively. Filters were applied to limit results to human studies published in English.

The Boolean MeSH keywords inputted on databases for this study are: ("diagnostic imaging"[MeSH Subheading] OR ("diagnostic"[All Fields] AND "imaging"[All Fields]) OR "diagnostic imaging"[All Fields] OR "ultrasonography"[All Fields] OR "ultrasonography"[MeSH Terms] OR "ultrasonographies"[All Fields]) AND ("elasticity imaging techniques"[MeSH Terms] OR ("elasticity"[All Fields] AND "imaging"[All Fields] AND "techniques"[All Fields]) OR "elasticity imaging techniques"[All Fields] OR "elastographies"[All Fields] OR "elastography"[All Fields]) AND (("liver"[MeSH Terms] OR "liver"[All Fields] OR "livers"[All Fields] OR "liver s"[All Fields]) AND ("biopsie"[All Fields] OR "biopsy"[MeSH Terms] OR "biopsy"[All Fields] OR "biopsied"[All Fields] OR "biopsies"[All Fields] OR "biopsy s"[All Fields] OR "biopsying"[All Fields] OR "biopsys"[All Fields] OR "pathology"[MeSH Subheading] OR "pathology"[All Fields])) AND ("liver cirrhosis"[MeSH Terms] OR ("liver"[All Fields] AND "cirrhosis"[All Fields]) OR "liver cirrhosis"[All Fields] OR ("liver"[All Fields] AND "fibrosis"[All Fields]) OR "liver fibrosis"[All Fields]) AND (y_10[Filter])

STUDY SELECTION

An initial screening of titles and abstracts is then conducted to exclude studies that clearly do not meet the inclusion criteria. This stage is performed independently by two or more reviewers to minimize bias and ensure objectivity. Studies that pass this preliminary screening are retrieved in full text for a more detailed assessment. During the full-text review, the reviewers carefully evaluate the studies against the inclusion and exclusion criteria. Any discrepancies between reviewers are resolved through discussion or by consulting a third reviewer to reach a consensus, ensuring that only the most relevant and high-quality studies are selected.

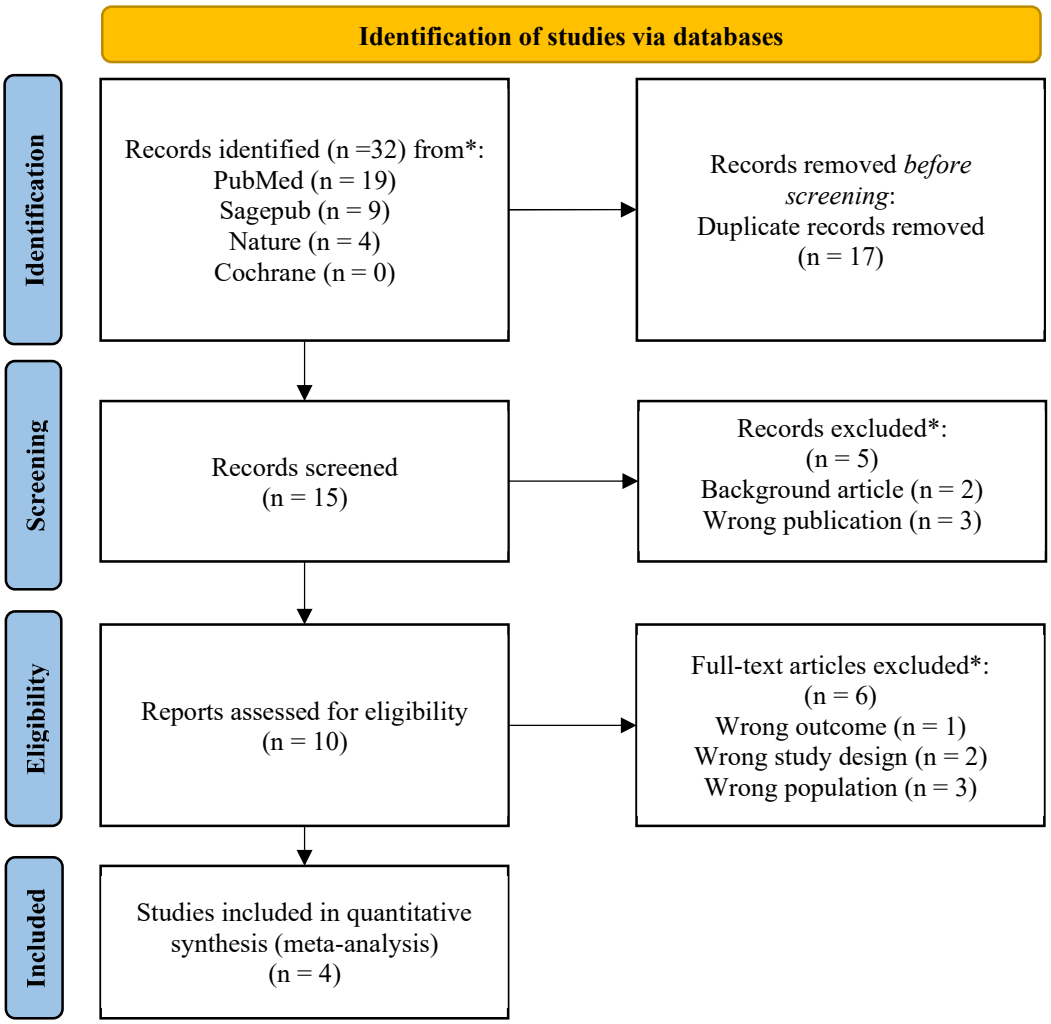

Figure 1. Search strategy and selection of studies for the meta-analysis.

DATA EXTRACTION

Data extraction was performed in duplicate from full-text versions of eligible studies by authors. Information regarding the comparison of diagnostic accuracy of ultrasound elastography techniques compared to liver biopsy for detecting liver was extracted at various time intervals. Data presented in tabular format were the primary source for extraction.

RISK OF BIAS

The risk of bias in each trial was assessed across six domains using the RevMan 5.4 tool (Cochrane, UK). These domains included sequence generation, allocation concealment, blinding, attrition bias, selective outcome reporting, and other potential sources of bias. Trials were categorized as having high, low, or unclear bias in each domain, with detailed justifications provided for each determination.

DATA SYNTHESIS AND ANALYSIS

The core of the data synthesis in this study involves statistical analysis, with the primary outcome measure being the diagnostic accuracy of ultrasound elastography techniques compared to liver biopsy for detecting liver fibrosis. The sensitivity and specificity are used to assess diagnostic performance. A fixed-effect model is applied to combine data from individual studies, assuming a consistent true effect size and that observed variations are due to sampling errors.

A forest plot visually presents the sensitivity and specificity estimates with their confidence intervals for each study, facilitating a comparison of results and an overall summary estimate. The pooled effect size is calculated from these individual estimates. In addition, a summary receiver operating characteristic (SROC) plot is generated to summarize the overall diagnostic accuracy of ultrasound elastography across studies, illustrating the trade-off between sensitivity and specificity.

Meta-analysis is performed using a fixed-effect model, and statistical analyses, including the SROC plot generation, are conducted using Review Manager Software version 5.4 (Nordic Cochrane Centre, Cochrane Collaboration, Copenhagen, Denmark).

RESULT

A total of 32 articles were retrieved from online databases (PubMed, SagePub, Nature and Cochrane). After three rounds of screening, four articles directly relevant to the systematic review were selected for full-text reading and analysis. The characteristics of the studies are showed in Table 1 and 2

Table 1. Characteristics of studies included in the systematic review

Author	Origin	Study Design	Sample Size	Result
Atzori, et al.[19] (2024)	UK	Retrospective cohort study	160 patients	The number of liver stiffness measurements (LSM) needed for reliable results was found to be reduced to 6 for ElastPQ and 7 for VTQ, compared to the standard recommendation of 10. Significant fibrosis and an interquartile range/median (IQR/M) ratio greater than 30 were identified as independent predictors of lower reliability in detecting liver fibrosis. Ordinal logistic regression, adjusted for age, showed significant interactions between steatosis ($p = 0.008$) and lobular inflammation ($p = 0.04$) with VTQ (ARFI), as well as between lobular inflammation and transient elastography (TE) ($p = 0.006$).
Conti, et al.[20] (2019)	Italy	Retrospective cohort study	160 patients	ElastPQ values showed a strong correlation with histological detection of fibrosis ($r = 0.718$, $P < .001$). The area under the receiver operating characteristic (AUROC) values were 0.856 for detecting significant fibrosis (F≥2), 0.951 for advanced fibrosis (F≥3), and 0.965 for cirrhosis. The optimal cut-off values for classifying patients with F≥2, F≥3, and cirrhosis were 6.0 kPa, 6.2 kPa, and 9.5 kPa, respectively, which were lower than those identified for transient elastography (TE). Both ElastPQ and TE had comparable diagnostic accuracy across all stages of liver fibrosis and outperformed non-invasive scores like the aspartate transaminase to platelet ratio index (APRI) and fibrosis-4 (FIB-4) index ($P < .05$ for all AUROC comparisons).
Gharibvand, et al.[21] (2020)	Iran	Retrospective cohort study	176 patients	There was a strong correlation between liver stiffness and fibrosis stage ($\rho = 0.939$, $P < 0.0001$). The area under the ROC curve (AUC) values were 0.871 for fibrosis stage F2, 0.895 for F3, and 0.937 for F4. The optimal cutoff values for detecting fibrosis stages were 8.6 kPa for F2, 10.7 kPa for F3, and 13.8 kPa for F4. Sensitivity and specificity were 81.76% and 77.01% for F2, 90.20% and 78.40% for F3, and 89.53% and 94.38% for F4, respectively.

Tada, et al.[22] (2015)	Japan	Retrospective cohort study	55 patients	The median shear wave elastography (SWE) elasticity values, FIB-4 index, APRI, and Forns' index for fibrosis stages F0–F1 and F2–F3 were 6.3 kPa and 13.1 kPa, 1.52 and 4.45, 0.41 and 1.43, and 7.69 and 8.85, respectively ($P < 0.001$ for all). Multivariate analysis revealed that SWE was independently associated with significant liver fibrosis (odds ratio: 2.52, 95% CI: 1.49–4.28, $P < 0.001$). The area under the ROC curve for SWE in diagnosing significant fibrosis was 0.94, indicating high diagnostic value, compared to 0.86, 0.88, and 0.83 for the FIB-4 index, APRI, and Forns' index, which showed moderate diagnostic value. The diagnostic accuracy was 90.9% for SWE, 76.4% for the FIB-4 index, 74.5% for APRI, and 67.2% for Forns' index.
Zayadeen, et al.[23] (2022)	Jordan	Retrospective cohort study	95 patients	The study included 95 patients with a mean age of 30 years (range 3–65). Of these, 16% had hepatitis B or C, 64% had another liver disease, and 20% were donors. The mean liver stiffness measured by elastography was 6.5 ± 0.19 kPa. For different fibrosis stages, the mean liver stiffness was 5.39 ± 0.62 kPa for F0–F1, 7.32 ± 0.41 kPa for F2, 8.46 ± 0.33 kPa for F3, and 11.42 ± 2.8 kPa for F4. A significant difference was observed in liver stiffness across the various fibrosis stages ($p = 0.0001$).

Table 2. Characteristics of studies included in the meta-analysis

No.	Author	Country	Study Design	Total Sample	Positives		Negatives		Sensitivity	Specificity
					True	False	True	False	(Fixed, 95%CI)	(Fixed, 95%CI)
1.	Atzori, et al.[19] (2024)	UK	Retrospective cohort study	160 patients	39	13	13	39	0.75 [0.61, 0.86]	0.75 [0.61, 0.86]
2.	Conti, et al.[20] (2019)	Italy	Retrospective cohort study	160 patients	55	66	13	227	0.81 [0.70, 0.89]	0.77 [0.72, 0.82]
3.	Gharibvand, et al.[21] (2020)	Iran	Retrospective cohort study	176 patients	40	30	4	102	0.91 [0.78, 0.97]	0.77 [0.69, 0.84]
4.	Tada, et al.[22] (2015)	Japan	Retrospective cohort study	55 patients	16	3	2	34	0.89 [0.65, 0.99]	0.92 [0.78, 0.98]
5.	Zayadeen, et al.[23] (2022)	Jordan	Retrospective cohort study	95 patients	12	10	25	48	0.32 [0.18, 0.50]	0.83 [0.71, 0.91]

The risk of bias analysis for the included studies on liver stiffness measurement (LSM) and fibrosis detection using ElastPQ, VTQ, and other shear wave elastography (SWE) methods was conducted using the RevMan 5.4 tool, developed by Cochrane, UK, and is presented in Figure 2 and Figure 3. The risk of bias assessment for studies such as Atzori et al. (2024), Conti et al. (2019), Gharibvand et al. (2020), Tada et al. (2015), and Zayadeen et al. (2022) reveals a consistent pattern of moderate risk.

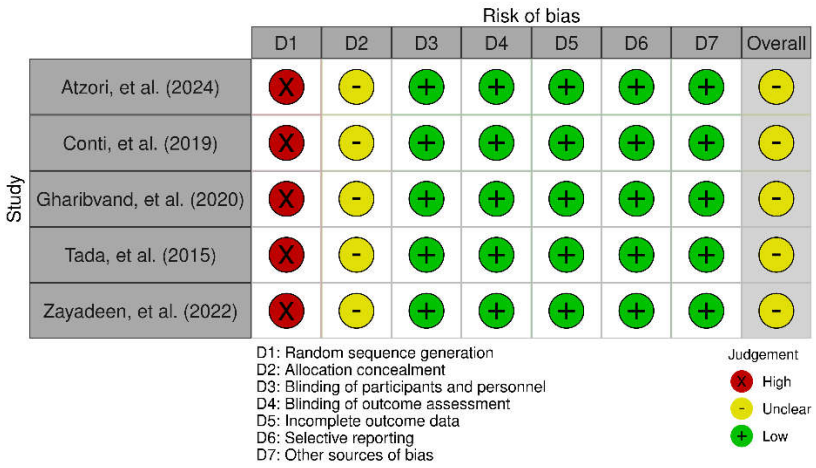

Figure 2. Risk of bias summary: review authors' judgements about each risk of bias item for each included study.

These retrospective cohort studies were all marked by a high risk in the domain of random sequence generation, as their non-randomized design inherently lacks this feature. Allocation concealment was also not applicable in these studies. However, they consistently demonstrated low risk in the areas of blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, and selective reporting. These studies had objective outcomes, such as liver stiffness and fibrosis stages, which were measured with standardized tools, minimizing measurement bias.

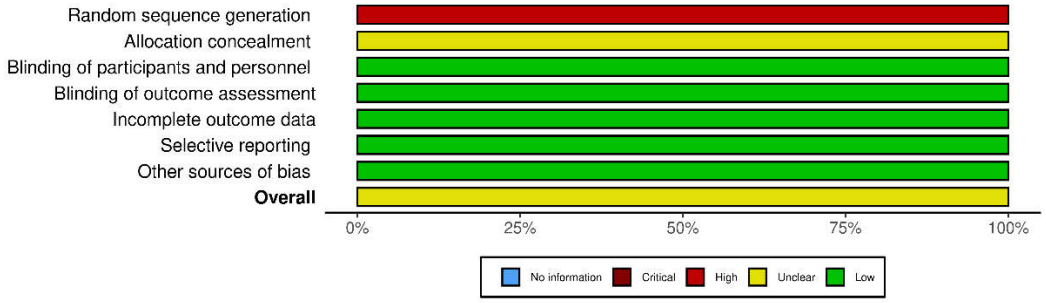

Figure 3. Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.

Overall, while these studies showed robustness in several areas, the inherent design limitations of retrospective studies lead to an overall moderate risk of bias. The lack of randomization and allocation concealment should be considered when interpreting the results, even though the objective nature of the outcomes mitigates some of these risks. As such, these findings should be viewed with caution, and future studies should aim to employ more rigorous methodologies to further strengthen the evidence for the diagnostic accuracy of liver stiffness measurements.

Sensitivity and Specificity of Ultrasonography Elastography for Detecting Liver Fibrosis Compared to Liver Biopsy

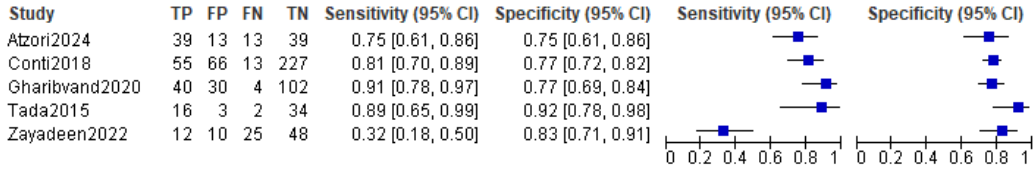

Figure 4. Forest Plot: Sensitivity and Specificity of Ultrasonography Elastography for Detecting Liver Fibrosis Compared to Liver Biopsy

The forest plot provides a summary of the sensitivity and specificity of liver stiffness measurements (LSM) for detecting liver fibrosis across five studies: Atzori2024, Conti2018, Gharibvand2020, Tada2015, and Zayadeen2022. Each study reports the sensitivity and specificity of their diagnostic tests along with 95% Confidence Intervals (CIs), allowing for a comparison of their diagnostic performance.

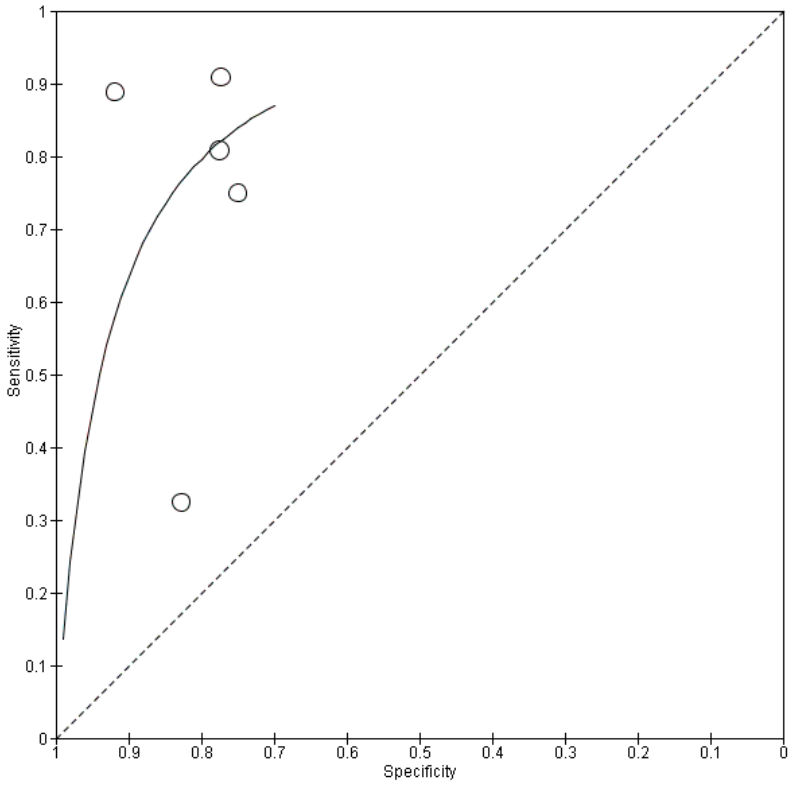

Figure 5. SROC plot

Atzori2024 reported a sensitivity of 0.75 [0.61, 0.86] and a specificity of 0.75 [0.61, 0.86]. These findings indicate a moderate ability of LSM to both correctly identify cases of fibrosis and exclude cases without fibrosis. In contrast, Conti2018 demonstrated a higher sensitivity of 0.81 [0.70, 0.89] and a specificity of 0.77 [0.72, 0.82], reflecting a strong overall diagnostic performance. This suggests that Conti2018's LSM is particularly effective in detecting fibrosis while maintaining a reasonable rate of correctly identifying non-fibrosis cases.

Gharibvand2020 exhibited the highest sensitivity at 0.91 [0.78, 0.97], but with a lower specificity of 0.77 [0.69, 0.84]. This indicates that while Gharibvand2020's LSM excels in detecting fibrosis, it is less effective at ruling out cases that do not have fibrosis, which may lead to more false positives. Tada2015 provided robust diagnostic accuracy with a sensitivity of 0.89 [0.65, 0.99] and a high specificity of 0.92 [0.78, 0.98]. These values reflect both strong sensitivity and specificity, indicating a well-balanced diagnostic performance. On the other hand, Zayadeen2022 had the lowest sensitivity of 0.32 [0.18, 0.50], but reported a higher specificity of 0.83 [0.71, 0.91]. This suggests that while Zayadeen2022's LSM is less effective at detecting fibrosis, it performs reasonably well in correctly identifying non-fibrosis cases.

Overall, the performance of LSM in detecting liver fibrosis varies across studies. Gharibvand2020 demonstrated the highest sensitivity, while Tada2015 showed the most balanced performance between sensitivity and specificity. Zayadeen2022, with its lowest sensitivity, indicates that it may be less effective in accurately detecting fibrosis compared to the other studies.

DISCUSSION

The diagnostic performance of liver stiffness measurements (LSM) for detecting liver fibrosis shows notable variability across different studies. Atzori et al. (2024) report moderate sensitivity and specificity for LSM, indicating a reasonable capacity to both identify and exclude cases of liver fibrosis. This reflects the effectiveness of LSM but also highlights its limitations in diagnostic precision. Their study is unique in comparing multiple ultrasound-based methodologies side-by-side, revealing that optimization of measurement protocols is crucial for enhancing reliability. This is further supported by the real-world evidence that non-invasive methods such as shear wave elastography (SWE) have become increasingly significant in clinical practice.[19]

In contrast, Conti et al. (2018) found that LSM achieved enhanced sensitivity, suggesting that their method is particularly effective in detecting fibrosis while maintaining a reasonable rate of correctly identifying non-fibrosis cases. This strong overall diagnostic performance underscores the utility of ElastPQ and TE, which have been shown to outperform other non-invasive scores. The correlation between ElastPQ values and histological detection of fibrosis supports the superior diagnostic accuracy of this method, aligning with the findings of other studies that emphasize the importance of accurate measurement techniques in liver fibrosis diagnosis.[20]

Gharibvand et al. (2020) presented data with high sensitivity but lower specificity, indicating a trade-off in diagnostic performance. This suggests that while their LSM is highly effective in detecting fibrosis, it may also result in a higher rate of false positives. This concern is echoed in previous literature, where variations in diagnostic accuracy were noted due to differences in methodologies and patient demographics. The trade-off between sensitivity and specificity remains a critical factor in evaluating the overall effectiveness of LSM techniques.[21]

The balanced performance reported by Tada et al. (2015) with both high sensitivity and specificity indicates that their LSM provides robust detection of significant fibrosis and accurate exclusion of non-fibrosis cases. This performance is consistent with previous findings that highlight the high diagnostic accuracy of SWE. Their results underscore the potential of SWE to offer a reliable alternative to liver biopsy for diagnosing liver fibrosis, provided that measurement techniques are optimized.[22]

On the other hand, Zayadeen et al. (2022) reported lower sensitivity but higher specificity, suggesting that their LSM may be less effective in detecting fibrosis while performing well in ruling out non-fibrosis cases. This limitation points to the need for improvements in the sensitivity of LSM methods, as the lower sensitivity could lead to missed diagnoses of true fibrosis cases. This concern reflects findings from other studies that highlight the variability in diagnostic accuracy among different LSM techniques.[23]

The impact of measurement protocols on diagnostic accuracy is further highlighted by Atzori et al. (2024), who found that reducing the number of liver stiffness measurements needed for reliable results could enhance accuracy. Their comparison of various ultrasound techniques underscores the importance of refining measurement procedures to improve LSM effectiveness. This finding supports the need for standardized protocols to optimize diagnostic performance across different techniques.[19,24,25]

The correlation between ElastPQ values and histological detection of fibrosis, as reported by Conti et al. (2018), indicates that this method offers superior diagnostic accuracy. This finding is consistent with the good diagnostic performance of ElastPQ and TE observed in a heterogeneous population, while VTQ (ARFI) showed lower accuracy. The high diagnostic performance of ElastPQ and TE reinforces their potential as reliable non-invasive alternatives to liver biopsy.[22]

Gharibvand et al. (2020) demonstrated that LSM is effective in staging liver fibrosis across different stages. However, the discrepancies between SWE measurements and histology results highlight the need for careful interpretation due to sampling errors and methodological differences. These discrepancies suggest that while LSM provides valuable information, it should be used in conjunction with other diagnostic methods to ensure comprehensive evaluation.[21]

Overall, the utility of LSM as a non-invasive alternative to liver biopsy varies based on technique and thresholds used. Future research should focus on standardizing LSM protocols and validating these methods to improve their diagnostic accuracy and clinical utility. Continued investigation into the influence of factors such as liver steatosis and inflammation, as well as comparisons between different LSM techniques, will be essential for optimizing liver fibrosis diagnosis and enhancing patient care. [26,27]

CONCLUSION

Ultrasonography elastography offers a non-invasive alternative to liver biopsy for detecting fibrosis with generally good accuracy. However, variability in diagnostic performance and the need for standardized protocols suggest it should complement rather than replace liver biopsy.

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